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510(k) Summary

AUG 16 2011

Applicant / Sponsor: DePuy Orthopaedics Inc.  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988  
Establishment Registration No.: 1818910

Contact Person: Nancy S. Friddle  
Project Manager, Regulatory Affairs  
Tel: (574) 371-4923  
Fax: (574) 371-4987

Proprietary Name: TruMatch™ Personalized Solutions

Common Name: Total Knee Prosthesis

Classification Name: 21 CFR 888.3560: Knee joint patellofemorotibial  
polymer/metal/polymer semi-constrained cemented prosthesis.  
Class II

Product Code: JWH

Subsequent Product Code: OOG

Device Description:

Subject of this premarket notification are TruMatch™ Patient Specific Instruments which are designed and manufactured from patient imaging data and used with other DePuy Orthopaedics implants.

Indications and Intended Use:

The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.

The anatomical landmarks necessary for the creation of the TruMatch™ Patient Specific Instruments must be present and identifiable on CT.

The TruMatch™ Patient Specific Instruments are intended for use with Sigma® Total Knee Implants and Attune™ Total Knee Implants and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only.

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Summary of Technologies/Substantial Equivalence:

The TruMatch™ Patient Specific Instruments have the same indications, intended use, similar design and are substantially equivalent to the Smith & Nephew's Patient Matched Cutting Blocks and also to the traditional instruments that are associated with the Sigma® and Attune™ cleared knee implant systems. The TruMatch™ Patient Specific Instruments are used in conjunction with the DePuy Orthopaedics, Inc Sigma and Attune implant systems identified in the table below.

System	510k	Clearance Date
Sigma Total Knee System	K882234	10/20/1988
	K884796	3/29/1989
	K943462	12/21/1994
	K950010	5/15/1995
	K944538	9/26/1995
	K961685	7/10/1996
	K961685	7/10/1996
	K971189	7/17/1997
	K971189	7/17/1997
	K082500	11/18/2008
Attune Total Knee System	K101433	12/10/2010

Non-Clinical Testing:

The following testing was performed to demonstrate the substantial equivalence of the TruMatch™ Patient Specific Instruments to the predicate devices.

- TruMatch™ Dimensional Stability Test
- Cadaver Accuracy Study
- Design Process and Design Software Repeatability Study
- Software Validation and Verification Summary

The tests results demonstrate that all acceptance criteria were met.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the TruMatch™ Patient Specific Instruments and the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -W066-G609  
Silver Spring, MD 20993-0002

DePuy Orthopaedics, Inc.  
% Ms. Nancy S. Friddle  
Project Manager, Regulatory Affairs  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

AUG 16 2011

Re: K110397

Trade/Device Name: DePuy TruMatch™ Patient Specific Instruments

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint patellofemoral tibial polymer/metal/polymer semi-constrained  
cemented prosthesis

Regulatory Class: Class II

Product Code: JWH, OOG

Dated: June 15, 2011

Received: June 16, 2011

Dear Ms. Friddle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

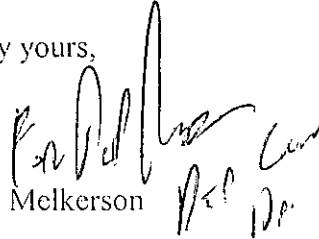
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic,  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K110397

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## 2. INDICATIONS FOR USE

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510(k) Number (if known): \_\_\_\_\_

Device Name: DePuy TruMatch™ Patient Specific Instruments

### Indications for Use:

The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.

The anatomical landmarks necessary for the creation of the TruMatch™ Patient Specific Instruments must be present and identifiable on CT.

The TruMatch™ Patient Specific Instruments are intended for use with Sigma® Total Knee Implants and Attune™ Total Knee Implants and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

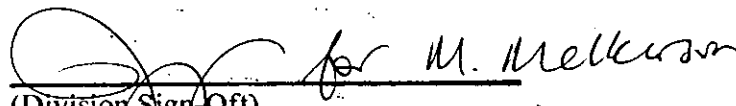
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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